



Food and Drug Administration
Rockville, MD 20857

Re: DIFFERIN Solution (5,212,303)
Docket No. 96E-0353

DEC 20 1996

#12

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,212,303, filed by Centre International de Recherches Dermatologiques ("CIRD"), under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for DIFFERIN Solution, the human drug product claimed by the patent.

The total length of the regulatory review period for DIFFERIN Solution is 2,814 days. Of this time, 1,651 days occurred during the testing phase and 1,163 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective:
September 18, 1988.

FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on September 18, 1988.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: March 26, 1993.

The applicant claims March 19, 1993, as the date the New Drug Application (NDA) for DIFFERIN Solution (NDA 20-338) was initially submitted. However, FDA records indicate that NDA 20-338 was submitted on March 26, 1993.

3. The date the application was approved: May 31, 1996.

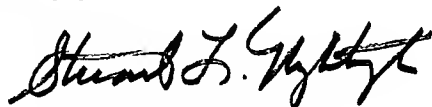
FDA has verified the applicant's claim that NDA 20-338 was approved on May 31, 1996.

DIFFERIN Solution - Page 2

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Stuart L. Nightingale". The signature is fluid and cursive, with a large initial "S" and "N".

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Norman H. Stepno
Burns, Doane, Swecker & Mathis, L.L.P.
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